Medical Device Regulatory Requirements for Korea

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Industry Definition

Medical devices in Korea include products used to diagnose, cure, alleviate, treat illness, injuries or disabilities; to prevent illness or to complement injuries or disabilities; to test, replace or alter structures or functions of the bodies; or for birth control. In Vitro Diagnostic (IVD) instruments and some reagents in it are classified as Class I products; however, most IVD reagents are categorized as pharmaceutical products. Separate regulatory approval procedures exist for IVD instruments and manual reagents.

Introduction to the Korean Regulatory System

The Ministry of Health and Welfare (MHW) is the primary healthcare agency regulating the importation of medical devices. Under Korea's Medical Devices Act, the Korea Food and Drug Administration (KFDA), an agency under MHW, independently regulates all medical devices; only when KFDA requests legislation to fulfill its mission is agreement with MHW required. The Medical Devices Act, passed by Korea's National Assembly in 2003, is now fully in force with the requirement that all medical devices sold in Korea meet Good Manufacturing Practices (KGMP—more on this topic below).

Imported medical devices require an original Certificate to Foreign Government (CFG) by the appropriate regulatory body in the product's country of manufacture before they can be sold in Korea. KFDA requires foreign manufacturers to have local partners or a physical presence (business registration, along with office and warehouse space) in Korea rather than interact with regulators directly. All foreign suppliers must apply for either a manufacturing or importer business license in order to market medical devices. To obtain a business license, an importer must provide a copy of KFDA Form 1, a health certificate of the company representative, a copy of the registered legal entity, and a list of facilities. An importer can have more than one distributor, but each distributor must either register as an importer, or have an independent consultant hold the product approval so each importer has equal access to it.

All medical devices require pre-market registration from KFDA before they can be manufactured locally or imported into Korea. There are two types of pre-market licenses: pre-market approval for Class II, III, and IV devices and pre-market notification for Class I devices. Pre-market approval requires a Technical File Review, Safety and Efficacy Review (SER—may be required for devices with new-to-market features), and Type Testing, while pre-market notification requires only a documentary review of product information (no testing is required). A Technical File Review is a "general" technical file review for those products that are basically the same as an already approved product

(similar to the U.S. 510-K approval), whereas a SER is required for devices unlike those currently available on the market (similar to the U.S. pre-market approval). KFDA now conducts a Technical File Review on all Class II, III, and IV products.

Other agencies involved with medical device regulatory issues include:

- The Health Insurance Reimbursement & Assessment Service (HIRA), which accepts and reviews applications for reimbursement approvals submitted by device manufacturers;
- the National Health Insurance Corporation (NHIC) which collects premiums and pays hospitals and pharmacies; and
- the Korean Testing Laboratory (KTL) http://www.ktl.re.kr/eng/html/c1.asp, which is the only accredited laboratory performing type testing for all 39 categories of medical devices available in the marketplace.

Besides KTL, KFDA has authorized nine other domestic laboratories to perform "type testing" on medical devices. However, each one has limitations on the scope of medical devices it can test, so identifying the laboratories appropriate for testing specific devices is essential. The nine laboratories are listed in the section titled "Step 2 - Type Testing."

KFDA has created a Medical Device Quality Management Team to oversee the Medical Device Act requirement that all medical devices must meet KGMP. KFDA believes importers, not manufacturers, should be primarily responsible for the quality of imported medical devices.

As of September 2008, complete details about KGMP have not been released; however, program features include a requirement that manufacturers will need KGMP certification in each category, and the certification will be in effect for three years. Importers will need recertification if they seek product notification or approval from a new manufacturer. KFDA expects to take one month from the initial application date to coordinate and schedule an audit, accompanied by a representative from KTL, the Korea Environmental and Merchandise Testing Institute (KEMTI), the Korea Testing and Research Institute for the Chemical Industry (KOTRIC) or the Korea Electric Testing Institute (KETI). The six KGMP categories are expected to be:

Devices Using No Electricity
Devices Using Electricity
Radiation Emitting Devices
Ray-Generating Devices
Medical Supplies
Dental Materials

Other regulatory areas currently being considered by KFDA include plans for periodic re-testing and post-market surveillance.

Korea uses four different medical device classifications, which harmonize most closely to the European Union (EU) system. There are some products that Korea considers medical

devices which the U.S. does not (including skin care/aesthetic equipment and high pressure water jet bathtubs), and vice versa. If a product is not listed in the Korean system but has been approved by the U.S. FDA, the authorized representative should contact the KFDA and ask for a classification determination. KFDA may take up to 90 days to decide on the request.

Registration with the Korea Food and Drug Administration (KFDA)

The following are general requirements for registering all medical devices in Korea:

- Product must be approved for sale in the country of origin (i.e. USA);
- local distributor (Korean importers or Korea-registered subsidiary of the US supplier rather than the US manufacturer/supplier) shall apply for and serve as legal holders of the registration;
- original USFDA Certificate to Foreign Government (CFG), including the brands and model/catalogue numbers of all products submitted for approval;
- notarized GMP certificates (TUV certificates);
- raw material specifications and standards; and
- catalogs/brochures.

Additional Requirements, by Product Class include:

Class I medical devices require only Pre-Market Notification, which involves:

- Classifying the device;
- providing Certificate of Free Sale; and
- the submission of Form 5 (to be completed by Korean importer) including:
    - Local importer information (company name, address and device business license number; local company representative and his/her resident registration number);
    - trade name, product name and classification name of device;
    - raw materials;
    - manufacturing methods;
    - dimensional drawings;
    - specifications of finished product;
    - packaging unit;
    - instructions and precautions for use;
    - labeling; and
    - foreign manufacturers' company name.

It takes about one to two months to complete the notification process.

Class II, III and IV medical devices require Pre-Market Approval, which involves:

- Classifying the device;
- providing Certificate of Free Sale;
    - **Step 1 – Technical Review**
        - Form 7, Medical Device Technical Documents Review Request including:

- Local importer's company name, address and device business license number; local company representative and his/her resident registration number;
- foreign manufacturer's company name, address and country of manufacture;
- product, model, and classification names of device;
- external appearance, internal structure, sizes;
- manufacturing methods;
- effectiveness, performance and purpose of use;
- instructions and precautions for use;
- packaging units;
- storage conditions, validity period;
- standards and test standards; and
- labeling.

In addition to submitting a Form 7 to KFDA, Class II, III and IV devices require a cover page and an attachment with a description of each supporting document. These documents include:

- Bench test reports;
- clinical trial reports;
- reference photocopies;
- relevant literature;
- information on physical/chemical characteristics;
- information on electric/mechanical safety;
- information on biological safety;
- information on radiation safety;
- information on electromagnetic interference (EMI); and
- rationales and test reports to confirm safety and product performance.

- During Step 1, KFDA may require a Safety and Efficacy Review (SER) for any product with new-to-market features in terms of materials, mechanisms of action, usage or effectiveness. A SER application includes the following additional information:
  - Information on origin, discovery, and background of development;
  - characteristics of device;
  - stability data;
  - information on use in foreign countries;
  - comparative analysis with similar products previously approved in the market; and
  - clinical study report (most important part of SER).

Other items about which U.S. companies should be aware include:

- The local clinical study is not important if foreign clinical data is strong enough to demonstrate safety and efficacy;
- KFDA will accept foreign clinical data if published in a Science Citation Index (SCI) listed journal; or
- the foreign government regulator has approved the clinical report, and documentation is provided.

In early 2006, Korea approved their first multinational clinical trial for medical devices (this has occurred with an increasing number of pharmaceuticals in recent years).

- **Step 2 – Type Testing (mandatory for Class II, III and IV devices)**
  Once the product passes Step 1, the technical review phase, it then must undergo type testing (i.e. a KFDA-authorized lab tests the product, or makes a determination that, based upon acceptable foreign data, the product does not require local testing in Korea):
  - Firm can initiate type testing before or during the technical file review process;
  - the testing must be done by a KFDA-approved third-party laboratory;
  - generally takes one to three months, depending on the nature of type testing done;
  - company must submit a copy of the draft or approved technical file, foreign test results (if available), and test samples to laboratories;
  - importers must file Form 2 to receive exemption to import unapproved devices for testing. Required information includes:
    - Candidate importer and manufacturer;
    - product name;
    - necessary quantity; and
    - name of test lab asked to carry out testing.

  - Typical test reports requested:
    - Biological Safety
      - Tests conducted must be carried out to meet ISO, ASTM and GLP standards
    - Electrical Safety
      - All testing must meet IEC standards;
      - to be exempt from local testing, IEC test reports must be submitted in the "CB scheme" form; and
      - reports must be certified by a National Certification Body Testing Laboratory
    - Performance Reports
      - A full description of test protocols, acceptance criteria, etc. is required;
      - raw data may be required on a case-by-case basis;
      - signature required by lab technicians and supervisors; and
      - notarized test reports are required.

KFDA Authorized Labs

Authorized Laboratory	Areas of Expertise
Korea Testing Lab (KTL)*	All medical devices
Korea Testing & Research Institute for Chemical Industry (KOTRIC)	14 product groups, including implants and supplies
Korea Electric Testing Institute (KETI)	27 product groups, including electronic/electric devices
Korea Merchandise Testing and Research Institute (KOMTRI)	14 product groups, including medical supplies
Seoul National University Hospital Clinical Trial Center	11 product groups, including implanted medical devices and supplies
Yonsei University Hospital Medical Technology Evaluation Center	11 product groups, including implanted medical devices and supplies
Yonsei University Dental College Dental Products Testing & Evaluation Center	Dental devices only
Kyung-hee University, Dental College, Open Laboratories for Dental Products	Dental Devices only

*KTL is the only KFDA authorized lab that handles all medical devices: http://www.ktl.re.kr/eng/html/c1.asp

- **Step 3 – Obtain Product License**
  - Two types of product license: manufacturer and importer
  - Form 3 is required to receive certificate of product approval from KFDA. Other items include:
    - Copy of approved technical file;
    - copy of approved type test;
    - list of facilities; and
    - Free Sale Certificate issued by government of country of manufacture.

- **Step 4 – Audit of Quality System/KGMP Certification**
  - Manufacturers must be certified by category;
  - importers must be re-certified before they have a notification or approval of a product made by a new manufacturer;
  - six proposed KGMP categories (appear above under "Introduction"—firms apply for KGMP certification using one of four KFDA-certified third-party labs (KTL, KEMTI, KOTRIC or KETI)); and
  - third-party organization coordinates with KFDA and sets audit dates

KFDA normally takes one month from application date to audit a firm.

A 510K-type approval normally takes four to six months. A PMA-type approval normally takes six to ten months.

Import Labeling

KFDA is now enforcing a law that all plastic medical instruments must mention on the product label if DEHP has been added or used in the process of the manufacture.

Key information that must appear on the device container includes:

- Business name and address of a manufacturer or importer;
- source of origin [name of manufacturer(s) and the country of manufacture] in case of an imported device;
- product name, type name (model name), product license or notification number;
- manufacturing (lot or batch) number and date of manufacture; and
- weight or packing unit.

Import Packaging

Key information that should appear on the outside packaging is the same as on the product label; packaging inserts should have the following information:

- Directions and precautions for use
- Information on technical maintenance
- Information required by KFDA Commissioner
- Other information required in the Ministerial Decree of the Ministry of Health and Welfare

Import Documentation

The sponsoring manufacturer or supplier of any U.S.-made medical device must provide its Korean importer with an original Certificate to Foreign Government (CFG) issued by the U.S. FDA. A CFG must be an original certificate that includes the brand names as well as model or catalog numbers of all products submitted for approval. Unlike U.S. regulations, which allow for minor additions and changes to previously approved products without pre-market approval from the FDA, KFDA requires an updated, original CFG when even minor changes are made to products. However, if changes to a product's catalog or model numbers are for administrative purposes only and not related to modifications of the product, KFDA will accept a foreign manufacturer's statement notarized by a state government.

KFDA does not have a U.S. FDA-like system to audit and verify company records on product changes, and views the requirement for accurate, updated CFGs as necessary to preclude the possibility of fraudulent applications. Specifically, the requirement prevents local importers from seeking medical device approvals without the foreign supplier's due authorization. Catalog or model numbers are also necessary for customs clearance purposes. Once a product has been approved, all the model or component numbers are

entered into a computer registry with which Korean Customs checks the approval status before it clears the import shipment.

U.S. medical suppliers must sell products in Korea through local distributors. They may not submit applications directly to KFDA. Since local manufacturers and distributors for imported medical devices both go through the same procedures to register and gain approval for medical devices sold in Korea, there are no additional documentation requirements for importers.

All application forms submitted to KFDA and to testing laboratories must be written in Korean. In addition, developing a constructive relationship with an experienced Korean importer is also important, as most responsible Korean officials do not understand English. It is also necessary to cultivate solid relationships with experienced regulatory professionals and government officials during the approval process.

In summary, all medical device classes require the following:

- Device business license (either for local manufacturer or import distributor)
- KGMP certification (although some provisions have not yet been finalized)

Class I medical devices also require notification to KFDA District offices and the submission of a Form 5 (referenced above). Once approval is received and a business license is obtained, the device can be brought into Korea. If an importer has already obtained a device business license for a company, it does not have to go through the process again for subsequent medical devices brought into Korea.

Class II/III/IV devices must go through the following additional steps:

- File review; two types are possible:
    - Technical File Review (when a device is basically same as previously approved products—510k-like review)
    - Safety and Efficacy Review (SER) (device significantly different than previously approved products—PMA-like review)
- Type Testing (using KFDA-approved lab)

Once these two steps are completed, then a product license is issued (either a manufacturer license or an importer license).

After this point, the device business license (only for a new-to-market company) and KGMP certification are the remaining steps, which are the same for all device classes. Until all KGMP provisions are released, it is unknown whether Class II/III/IV medical devices will be subject to more stringent requirements than Class I devices.

Contacts

U.S. firms wishing to learn more about regulatory issues related to medical devices in Korea are encouraged to contact the following agencies for additional information:

Korean Food and Drug Administration (KFDA)

Address: Medical Devices and Radiation Health Department
5 Nokbun-dong, Eunpyung-ku,
Seoul 122-704, Republic of Korea
http://www.kfda.go.kr/

Medical Device Evaluation & Approval Team
Phone: 82/2/380-1699, 1706, 1382
Fax: 82/2/380-1888

Contacts: Mr. RYU, Si-Han, Director, Medical Device Safety Team
Mr. YOO, Kyu-Ha, Director, Medical Device Evaluation & Approval Team

U.S. Foreign and Commercial Service Office—U.S. Embassy, Seoul

The Commercial Service (CS) Korea

Address: American Embassy, Seoul
Commercial Section
32 Sejong-ro, Chongro-ku
Seoul 110-710
Phone: 82/2/397-4439
Fax: 82/2/737-5357
Contacts: Yoon Shil Chay, Senior Commercial Specialist, or
Erik Hunt, Commercial Attaché
E-mails: Yoon.Shil.Chay@mail.doc.gov or Erik.Hunt@mail.doc.gov